

following receipt of such information. In supplemental reports, the manufacturer shall:

(a) Indicate on the form and the envelope, that the reporting form being submitted is a supplemental report. If the report being supplemented is an FDA Form 3500A report, the manufacturer must select, in Item H-2, the appropriate code for the type of supplemental information being submitted;

(b) Provide the appropriate identification numbers of the report that will be updated with the supplemental information, e.g., original manufacturer report number and user facility report number, if applicable;

(c) For reports that cross reference previous reports, include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s).

§ 803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and § 807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of § 803.50;

(3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(4) Maintain complaint files in accordance with § 803.18; and

(5) Register, list, and submit pre-market notifications in accordance with part 807 of this chapter.

[60 FR 63597, Dec. 11, 1995, as amended at 66 FR 23157, May 8, 2001]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, § 803.58 was stayed indefinitely.

EFFECTIVE DATE NOTE: At 70 FR 9519, Feb. 28, 2005, part 803 was revised effective July 13, 2005. For the convenience of the user, the revised text is set forth as follows:

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

803.1 What does this part cover?

803.3 How does FDA define the terms used in this part?

803.9 What information from the reports do we disclose to the public?

803.10 Generally, what are the reporting requirements that apply to me?

803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

803.12 Where and how do I submit reports and additional information?

803.13 Do I need to submit reports in English?

803.14 How do I submit a report electronically?

803.15 How will I know if you require more information about my medical device report?

803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?

803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?

803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?

803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

803.20 How do I complete and submit an individual adverse event report?

803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

803.22 What are the circumstances in which I am not required to file a report?

Subpart C—User Facility Reporting Requirements

803.30 If I am a user facility, what reporting requirements apply to me?